DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2019-N-5553]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Annual Summary Reporting Requirements Under the Right to Try Act

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or we) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Submit written comments (including recommendations) on the collection of information by [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be submitted to https://www.reginfo.gov/public/do/PRAMain. Find this particular information collection by selecting "Currently under Review - Open for Public Comments" or by using the search function. The OMB control number for this information collection is 0910-0893. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Domini Bean, Office of Operations, Food and Drug Administration, Three White Flint North, 10A-12M, 11601 Landsdown St., North Bethesda, MD 20852, 301-796-5733, PRAStaff@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Annual Summary Reporting Requirements Under the Right to Try Act

OMB Control Number 0910-0893

This information collection helps to implement provisions of the Federal Food, Drug, and Cosmetic Act (FD&C Act), added by the Right to Try Act, which requires sponsors and manufacturers who provide an "eligible investigational drug" under the Right to Try Act to submit to FDA an annual summary of such use. Regulations under § 300.200 (21 CFR 300.200) will require that sponsors and manufacturers submit to FDA an annual summary no later than March 31 of each year, including data for the preceding calendar year, that includes the following data elements:

- The name of the eligible investigational drug and applicable investigational new drug application number.
- The number of doses supplied to the eligible patient.
- The number of eligible patients treated.
- The use for which the eligible investigational drug was made available to the eligible patient.
- Any known serious adverse events and outcomes that the eligible patient treated with an eligible investigational drug experienced.

Description of Respondents: Respondents to the information collection are sponsors and manufacturers who provide an eligible investigational drug to eligible patients in accordance with the Right to Try Act and will submit to FDA annual summaries.

In the *Federal Register* of September 14, 2022 (87 FR 56269), we published a final rule (RIN 0910-AI36), including an analysis of the information collection, and discussed the development of an associated form to facilitate submission of the requisite information. Accordingly, we have developed Form FDA 5023 entitled "Right To Try Reporting Requirement: Annual Summary," which is currently available in the docket for comment purposes only, and we are inviting public comment. As required by the applicable statute,

section 561B of the FD&C Act (21 U.S.C. 360bbb-0a), the information is submitted to an FDA-designated point of contact, and in accordance with instructions to be posted at: https://www.fda.gov/patients/learn-about-expanded-access-and-other-treatment-options/right-try.

We estimate the burden of this collection of information as follows:

Table 1.--Estimated Annual Reporting Burden[1]

Activity; 21 CFR Citation	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response (in hours)	Total Hours
Sponsors and manufacturers submit annual summaries in accordance with the Right to Try Act (§ 300.200) using Form FDA 5023	6	1	6	2.5	15

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

Consistent with estimates in our Final Regulatory Impact Analysis for the associated final rule, we estimate that six sponsors and manufacturers will prepare and submit Form FDA 5023 and assume it takes 2.5 hours to prepare and submit each summary, which results in a total of 15 hours annually.

Dated: October 18, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

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